

succinate equivalent in activity to 10, 20, or 50 milligrams of prednisolone.

(c) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter for products containing 10, 20, and 50 milligrams equivalent prednisolone activity per milliliter for use in horses, dogs, and cats as provided in paragraphs (d)(1), (2) (i), (ii), and (iii) of this section. See No. 000402 in § 510.600(c) of this chapter for a product containing 10 milligrams equivalent prednisolone activity per milliliter for use in horses as provided in paragraph (d)(2)(iv) of this section.

(d) *Conditions of use.* (1) The drug is intended for the treatment of horses, dogs, and cats.¹

(2)(i) The dosage for horses is 50 to 100 milligrams as an initial dose given intravenously over a period of one-half to 1 minute, or intramuscularly, and may be repeated in inflammatory, allergic, or other stress conditions at intervals of 12, 24, or 48 hours, depending upon the size of the animal, the severity of the condition and the response to treatment.¹

(ii) In dogs, the drug is administered intravenously at a range of 2.5 to 5 milligrams per pound of body weight as an initial dose followed by maintenance doses at 1, 3, 6, or 10 hour intervals, as determined by the condition of the animal, for treatment of shock.

(iii) In dogs and cats, the drug may be given intramuscularly for treatment of inflammatory, allergic and less severe stress conditions, where immediate effect is not required, at 1 to 5 milligrams ranging upward to 30 to 50 milligrams in large breeds of dogs. Dosage may be repeated in 12 to 24 hours and continued for 3 to 5 days if necessary. If permanent corticosteroid effect is required oral therapy with prednisolone tablets may be substituted.

(iv) In horses, 50 to 100 milligrams as an initial dose given intravenously over a period of ½ to 1 minute. May be repeated in inflammatory, allergic, or other stress conditions at intervals of 12, 24, or 48 hours, depending upon the size of the animal, the severity of the

condition and the response to treatment. Not for use in horses intended for food. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered late in pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 13215, Feb. 20, 1981; 46 FR 33513, June 30, 1981; 52 FR 25212, July 6, 1987]

§ 522.1885 Prednisolone tertiary butylacetate suspension.

(a) *Specifications.* Prednisolone tertiary butylacetate (Pregna-1,4-diene-3, 20-dione-11B, 17α 21-triol 21-(3,3, dimethyl butyrate) suspension contains 20 milligrams of prednisolone tertiary butylacetate per milliliter. It is sterile.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an anti-inflammatory agent in horses, dogs, and cats.¹

(2) It is administered to horses intramuscularly at a dosage level of 100 to 300 milligrams and intrasynovially at a dosage level of 50 to 100 milligrams. It is administered intramuscularly to dogs and cats at a dosage level of 1 milligram per 5 pounds of body weight and intrasynovially at a dosage level of 10 to 20 milligrams. Intramuscular retreatment of horses in 24 to 48 hours may be necessary, depending on the general condition of the animal and the severity and duration of the disease.¹

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered late in pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997]

¹These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.